European Medicines Agency
Celebrating ten years – 1995 – 2005

"A Scientific Perspective on the Future of Medicines"

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Topic: The Patient's Perspective

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THE EUROPEAN MEDICINES AGENCY TENTH ANNIVERSARY

"A SCIENTIFIC PERSPECTIVE ON THE FUTURE OF MEDICINES"

The Patient's Perspective

by

Rodney Elgie
President
The European Patients' Forum

I am most grateful to the European Medicines Agency for the invitation to speak at this important event in order to put forward the patient's perspective on the future of medicines in the twenty-first century. May I also offer the EMEA my warmest congratulations on the occasion of its tenth anniversary.

History has clearly demonstrated the immeasurable value of medicines to mankind, especially over the latter half of the twentieth century. For example, at the time of the creation of the National Health Service in the UK in July, 1948, there were around 300 prescription medicines available to physicians and some 480,000 hospital beds. By the time of the NHS's Golden Jubilee in 1998, there were over 3,000 prescription drugs but the number of hospital beds had fallen to 190,000. It is inconceivable that these two figures are not inter-related. Thanks to medicines, more people can be treated with fewer hospital beds; additionally, fewer people require hospitalisation for their treatments today.

Having witnessed substantial changes in societal needs over the past century, we need a radical overhaul in the way healthcare is delivered today. In the first half of the twentieth century, the emphasis was on the control of infectious diseases such as polio and TB. The focus then switched to episodic care in the second half of the last century with the concentration on acute episodes such as heart attacks. For the first half of this century we need to look at chronic care, particularly those countries with a low GDP. Chronic conditions present the greatest challenge to practically all European states today. Interestingly, pharmacological interventions have been, and will continue to be, at the heart of healthcare.

There can be no underestimation of the importance of pharmacological interventions when considering the health of any nation. Medicines save lives, cure people and greatly enhance the quality of life for those patients with a chronic condition. But in a sense this pharmacological success can prove self-defeating or lead to the creation of other problems. Looming large and clear on national radar screens is the phenomena of an ageing population compounded by a lower birth rate. Many are predicting that by 2050 every three people in work will have to support two others in retirement plus those under twenty-one and still to be classified as producers or contributors to GDP.

Whilst celebrating the success and huge benefits that medicines have brought in the past, from the patient's perspective there are, perhaps, three caveats to observe when considering the future.

The first caveat is cost. We have heard from pharmaceutical companies how in 1997 it cost around US$500 million and took about ten years to bring a new drug to market. By 2000 these figures had moved upward to $700 million and twelve years. By the end of 2003 many in Europe were talking of a cost of 880 million Euros and a time span of thirteen years. If we project these figures forward to 2015, then it is quite possible that a new drug will cost $2.5 billion and take some eighteen years to bring to market. Is this sustainable? Within the UK it has been estimated that surgical procedures will no longer be required within the field of oncology by 2020 – all treatments will be pharmacological – but that the cost of such treatments in just this one area will bankrupt the NHS by 2025. I shall leave others far more expert in the field of health economics than I to debate this issue. Patients, however, are conscious of the frequently mentioned equation of cost effectiveness versus clinical effectiveness. We are mindful of the fact that if a medicine has too high a cost attached it will not secure authorisation for reimbursement. I made fleeting reference a moment ago to Europe's ageing population. One of the dilemmas challenging NICE in this country at present is whether to authorise an expensive drug for a cohort of patients in the mid to late 80s, or is it more cost effective to utilise the funds to treat other patients still in their 20s? There can be little doubt that this issue will only intensify in the coming years as the percentage of the population in the over 80 age bracket grows.

The second concern is compliance. If drugs are to cost so much to develop, then they must be used by patients more effectively and more efficiently than hitherto. There is little merit in debating terminology endlessly. Whether one chooses to call it compliance, concordance, adherence or alliance, the fact remains that across all chronic diseases, compliance ranges from 40% to 60%. There is no disease area where compliance is 90% and where we can examine what is done differently in this instance and then replicate that good practice in other therapeutic areas. Whilst compliance means different things to different people, for patients it is a question of taking the medicine as prescribed. Patients require more and better education in this area in order to accept a greater degree of responsibility for the management of their illness and its treatment.

There have been subtle changes to compliance barriers on the part of patients with chronic conditions in recent years. Thanks to the more modern medicines, initial side effects are a diminishing problem. Patients understand better today the mode of action of their medication and the fact that the body becomes used to the medicine's active ingredient. Of growing concern is what one might refer to as long-term side effects. For example, if I take this medication for several years will I become wholly dependent upon it, what effects will it have on the organs in my body such as my liver or kidneys, will it cease to work and will I become immune to it? With future medicines we need improved information programmes for patients to reduce the unacceptably high wastage levels occasioned through poor compliance. The DIA have estimated that the level of wastage in 2003 almost equalled the whole R&D budget of big pharma in that year! Surely, this is wholly unacceptable.

The third caveat centres around innovation, expectations and safety. Patients want to know that a drug is safe for them to take and recent press reports have served only to raise alarm in this respect.

Greater transparency over clinical trails will significantly ameliorate this situation. The press reports have also called into question the value and sufficiency of pharmacovigiliance. By definition, patients are not physicians or pharmacists and much available data are well beyond their sphere of comprehension. Patients simply want assurance that a medicine will not do them harm. The advent of genomics will see even greater, and possibly faster, advances in pharmacological innovation. This is to be welcomed,

especially in the area of rare diseases where previously no treatment existed. It is a real cause for hope by an army of such sufferers. In the world of Utopia, patients would like to see treatments available for all known conditions, for medications to be available which require the taking of one pill a month, for that pill to be effective immediately and for that medicine to be free from all side effects.

But on the downside, when the talk by European institutions is of quality, safety and efficacy, patients know that cost generally governs everything. We have seen many examples of this across Europe in recent years, the vast majority of which produce false or economic illusions. In the year 2000 there was much debate on the issue of essential similarity where, to circumvent data protection in some EU Member States, a different salt was used with the active ingredient to produce what I called a false generic. Today, the talk is of biosimilars but the principles remain the same – the drug must be thoroughly tested and required to go through an extensive examination process prior to human consumption. As Louis Pasteur remarked nearly a century and a half ago "The freedom of creative imagination must necessarily be subjected to rigorous experimentation" and "Extraordinary claims require extraordinary evidence". If ever the public lose faith in prescribed medicines, a compliance rate of even 40% will be difficult to achieve. Hence, we all have a vested interest in the success and safety of future medicines.

I must congratulate the EMEA on its foresight in having involved patients in its deliberations from an early date. This was a brave move and some might claim an act of faith on their part. It has been greatly appreciated by pan-European patient groups and I hope that the exercise has proved beneficial to the EMEA. I believe that by this transparent and democratic approach some of the fears I have outlined can be overcome for the benefit of patients, providers and payers. Medicines are our future and we, as patients, need to work in partnership with the pharmaceutical companies to convince the sceptics that health should be viewed as an investment, not a cost. If one thinks that health is expensive, then try ill health. To that end, we seek to encourage the pharmaceutical industry to continue along its innovative path and to involve patients where ever appropriate. Research should be a dialogue between society and science if it is to adequately address the needs of society in the 21st century. Within the European Patients' Forum our earnest hope is that we can continue to make a meaningful contribution to the work of the EMEA in all its facets and expand on the relationship that has been developed in recent years. The future of medicines is bright despite the caveats I have outlined. The desire for more and improved treatments has never been greater and we look in the main to the pharmaceutical industry to maintain in this century the claim that was made almost two centuries ago that "Laboratories are the temples of the future; the way to wealth and well-being".